

REMARKS

The present application contains claims 1-254, the status of which is as follows:

- (a) Claim 7 is as originally filed.
- (b) Claims 6, 55-56, 60-64, 151, 155, 161-164, 166-168, 172-174, 177, and 208 were previously presented.
- (c) Claims 59 and 175-176 have been currently amended.
- (d) Claims 152-154, 156-160, 165, and 169-171 were withdrawn in response to a restriction requirement.
- (e) Claims 1-5, 8-9, 16-54, 57-58, 65-150, and 178-204 were previously canceled, and claims 10-15, 205-207 and 209-214 have been currently canceled without prejudice. The Applicant reserves the right to prosecute these claims in future applications.
- (f) Claims 215-254 are new.

No new matter has been added. Reconsideration is respectfully requested.

Applicant thanks Examiner Evanisko for the courtesy of a personal interview with Applicant's representative, Sanford T. Colb (Reg. No. 26,856), held in the USPTO on May 5, 2008. At the interview, Mr. Colb presented two proposed amendments to claim 10 to further distinguish the claim from US Patent 5,683,429 to Mehra. The Examiner argued that these amendments represented an intended use of the apparatus recited in claim 10, but agreed to consider the amendments if made to the corresponding method claim (claim 59). Mr. Colb also presented arguments in favor of the existence of support for an amendment to claim 205 to recite that the applied signal is *only* cathodic or anodic. The Examiner maintained his position that the specification as filed does not provide adequate support for such an amendment.

Allowance of claims 6, 7, 55, and 56

Applicant again thanks the Examiner for allowing claims 6, 7, 55, and 56 in the official actions dated October 19, 2005, July 6, 2006, June 20, 2007, and February 14, 2008.

Claim rejections under 35 U.S.C. 112

Claims 12, 13, 61, and 62 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant has canceled claims 12 and 13, so the rejection of these claims is moot. The Applicant respectfully traverses the rejection of claims 61 and 62. The "period" of the train is not synonymous with the "duration" of the train, as argued by the Examiner. Instead, the "period" of the train is the interval between the commencement of successive pulses within the train of pulses, i.e., the reciprocal of the frequency of the pulses within the train of pulses. The specification provides this definition of "period" in several passages, including:

The pulse train preferably has a repetition frequency between 50 and 200 Hz (period between 5 and 20 ms). . . (p. 16, final paragraph).

In those preferred embodiments of the present invention wherein the extended pacing signal comprises a periodic waveform, the waveform preferably has a period of at least 2 ms (i.e., repetition frequency of 500 s⁻¹), more preferably at least 10 ms, and most preferably at least 20 ms (p. 5, final paragraph).

Claim rejections under 35 U.S.C. 102(b) over Whigham et al.

Claims 205, 206, and 209-214 were rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 4,821,724 to Whigham et al. While disagreeing with this rejection, the Applicant has canceled these claims in order to expedite issuance of a patent on other claims believed to be allowable.

Claim rejections under 35 U.S.C. 102(e) over Mehra

Claims 10-13, 15, 59-62, 64, 151, 155, 161-164, 166-168, 172, 173, 175, 176, and 177 were rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 5,683,429 to Mehra.

While disagreeing with the rejection of independent method claim 59, Applicant has amended the claim to recite that the electrodes are applied to, and the extended pacing signal is conveyed to, a ventricle of the heart. In contrast, Applicant respectfully submits that Mehra teaches his technique only for atrial pacing. For example, the title of the Mehra patent is "Method and apparatus for cardiac pacing to

prevent atrial fibrillation," and Mehra begins his Summary of the Invention by stating that "It is therefore an object of the present invention to provide a method and apparatus for preventing atrial fibrillation that may be otherwise triggered by an APB" (col. 5, lines 56-58). In addition, Mehra states that application of his signal is limited to the atria: "Unlike high voltage atrial defibrillation, the therapy provided by the present invention does not raise a corresponding risk of induction of ventricular tachyarrhythmia because the pacing pulse burst energy level is low and *confined to the atria*" (col. 6, lines 34-38; emphasis added).

Furthermore, Mehra teaches away from using his system for ventricular pacing, indicating that his system would be inappropriate for treating ventricular fibrillation, because the risk of a failure by his system to resolve ventricular fibrillation might be sudden death:

It is not envisioned that the pacing level therapy provided as discussed above will always be successful to prevent all atrial fibrillation episodes in any single patient. Repeated attempts, however, can be undertaken without severe consequences. *Unlike ventricular fibrillation, atrial fibrillation is not an immediately life threatening condition if prevention fails.* If the invention is embodied in a system which also includes high voltage atrial defibrillation capabilities, the pacing level therapy of the present invention may be employed as an initial therapy to prevent atrial fibrillation, with the intended goal of simply reducing the number of atrial fibrillation or flutter episodes subject to atrial defibrillation (col. 8, lines 22-34).

Applicant thus believes that claim 59, as amended, is allowable over Mehra. Claims 62, 64, 151, 155, 161-164, 166-168, 172, 173, 175, 176, and 177 are also in a condition for allowance, being of narrower scope than claim 59 from which they directly or indirectly depend.

Support for the amendment to claim 59 (and dependent claims 176-177) is provided in the specification as filed by at least the following:

In one such preferred embodiment, ... another of the electrodes, preferably in one of the ventricles, applies the extended pacing signals (p. 9, third full paragraph).

Two graphite vacuum electrodes were epicardially positioned at the left ventricle of the heart, and the pacing signal shown at the top of Fig. 5 was applied between the electrodes (p. 18, second full paragraph).

Furthermore, the specification as filed states, "... the application of the extended pacing signals can be incorporated into substantially any mode of pacing known in the art, including (but not limited to) VOO, VVI, OVO, VVT, VVIR, VDT, AOO, AAIR, ADI, VDD, DDD and DDTv pacing" (p. 9, third full paragraph). As is well known in the art, in the VOO, VVI, VVT, and VVIR pacing modes, the pacemaker paces only in the ventricle.

While disagreeing with the rejections of apparatus claims 10-13 and 15, Applicant has canceled these claims without prejudice in order to expedite issuance of a patent on other claims believed to be allowable, as discussed below.

Claim rejections under 35 U.S.C. 102(b) or 103(a) over Mehra

Claims 161-164, 166, 167, 172-174, and 176 were rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mehra. Applicant respectfully submits that these claims are allowable, because they directly or indirectly depend from allowable claim 59, as discussed above.

Claims 14, 63, 207, and 208 were rejected under 35 U.S.C. 103(a) as being unpatentable over Mehra. Claims 14 and 207 have been canceled. Applicant respectfully submits that claims 63 and 208 are allowable, because they directly or indirectly depend from allowable claim 59, as discussed above.

New claims

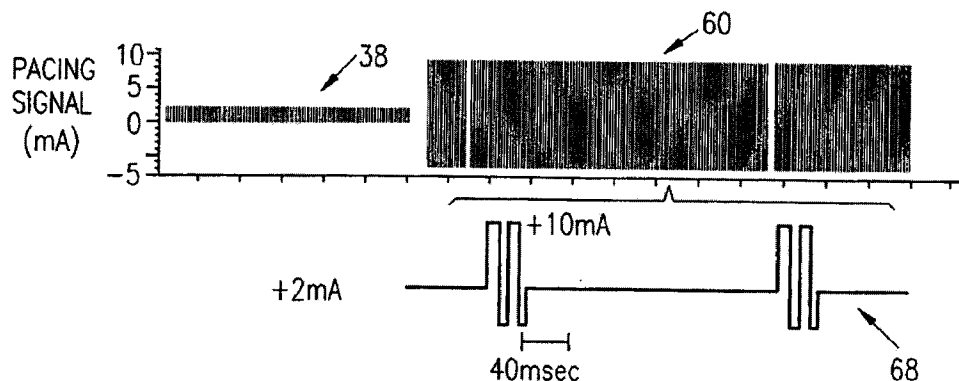
Claim 215 is new, and clarifies that "to pace the heart" has the conventional meaning of "pacing" in the art, i.e., initiating a plurality of consecutive heartbeats. Applicant respectfully submits that claim 215 is novel and non-obvious over Mehra and the other art known to Applicant. In particular, Mehra neither teaches nor suggests applying his anti-fibrillation signal to initiate consecutive heartbeats. The stated purpose of this signal is instead to prevent atrial fibrillation upon detecting an atrial premature beat (APB).

Claim 215 finds support throughout the specification as filed. For example, the specification states, ". . . the application of the extended pacing signals can be incorporated into substantially any mode of pacing known in the art, including (but not limited to) VOO, VVI, OVO, VVT, VVIR, VDT, AOO, AAIR, ADI, VDD, DDD and DDTv pacing" (p. 9, third full paragraph). These are well-known conventional pacing modes, which are modified to include the novel extended signal taught in the specification, and recited in claim 215, and which inherently initiate a plurality of consecutive heartbeats.

In addition, the application as filed provides explicit support for this feature:

Fig. 5 is a graph showing further experimental results, illustrating an increase in cardiac output due to pacing with extended pacing pulses, in accordance with a preferred embodiment of the present invention. An extended signal similar to signal 60 was then applied, In this case, as shown by an inset 68 in Fig. 5, the extended signal comprises two biphasic pulses, each beginning with an anodic pulse having an amplitude of about 10 mA, followed by a cathodic pulse of about 6 mA, with a DC level of about +2 mA. The overall signal duration T_2 was about 40 ms. Since the heart rate was held constant, at 180 beats/min, . . . (p. 18, second full paragraph).

The following is the relevant portion of Fig. 5:



As described in the specification and shown in this figure, Applicant's novel signal initiates a plurality of consecutive heartbeats. In particular, insert 68 in the figure shows the application of two consecutive signals (each including four pulses).

Claim 216 is supported as described above for the amendments to claim 59. Claims 217-251 depend from new claim 215, and are parallel to previously presented claims 60-64, 151-177, and 208, respectively. Claim 252 is supported as described above for new claim 215.

Claims 250, 251, 253, and 254 find support in the specification as filed at least by the following:

In preferred embodiments of the present invention, an improved cardiac pacemaker applies an extended pacing signal to the heart, the signal comprising a pacing pulse or a periodic waveform, preferably a train of pulses, having an overall duration substantially longer than a pulse duration required for pacing the heart. . . . Further preferably, the overall duration is greater than 8 ms, more preferably, greater than 10 ms, and most preferably, greater than 20 ms (p. 5, seventh full paragraph).

New claims 215-222, 226, 232-235, 237-239, 243-245, and 248-254 read on the elected inventions of the previously issued restriction requirements. New claims 223-225, 227-231, 236, and 240-242 have been withdrawn in accordance with the elections made in response to these previously issued restriction requirements.

Withdrawal of restriction requirement

Claims 152-154, 156-160, 165, 169-171, 223-225, 227-231, 236, and 240-242 were withdrawn in response to restriction requirements. Given the suggested patentability of independent claims 59 and 215, from which these non-elected claims directly or indirectly depend, the Applicant respectfully submits that the restriction requirement with respect to these withdrawn claims should be withdrawn (MPEP 821.04).

The Applicant believes the amendments and remarks presented hereinabove to be fully responsive to all of the grounds of rejection raised by the Examiner. In view of these amendments and remarks, the Applicant respectfully submits that all of the claims in the present application are now in order for allowance. Notice to this effect is respectfully requested.

Respectfully submitted,



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